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BIOPROSPECTION VERSUS BIOPIRACY AND THE UNITED STATES VERSUS BRAZIL: ATTEMPTS AT CREATING AN INTELLECTUAL PROPERTY SYSTEM APPLICABLE WORLDWIDE WHEN DIFFERING VIEWS ARE WORLDS APART—AND IRRECONCILABLE?

*Megan Dunagan**

THIS paper reviews the various legal perspectives regarding intellectual property rights and outlines attempts made by the United States and Brazil, as well as actions taken within international law, to reconcile patent law with the discovery and use of natural and/or living substances considered by some to be indigenous knowledge. Following the discussion of those viewpoints, the conclusion that indigenous resources and traditional knowledge must be acknowledged and protected is reached. And because the CBD, the U.N. Convention on Biodiversity, outlines an effective system for protection of indigenous resources and knowledge, its objectives should be incorporated into the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) in order to create the most effective international system.

Part I discusses the general concepts and rules relating to the regulation of intellectual property rights and the impact of patents on everyday life and specifically examines the state of intellectual property rules and laws in the United States. Part II looks at Brazilian laws regarding intellectual property rights and various international organizations' perspectives on patent rights and patentability. Part III examines the differences and distinctions between U.S. and Brazilian notions of intellectual property and each country's view on the patentability of certain substances (including a closer look at particular points of conflict between the two countries). Part IV discusses the varying perspectives regarding patents, nature, and intellectual property and outlines how the concept of bioprospecting differs from the concept of biopiracy. And Part IV also describes where the United States and Brazil weigh in on the biopiracy versus bi-

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oprospecting dichotomy. Part V considers the various suggested solutions regarding a worldwide system for patents and protection against biopiracy. Part V then discusses the possibility of overlapping the TRIPS Agreement requirements with those laid out in the CBD to effectively create an international system that can perhaps reconcile the varying viewpoints expressed by western societies, like the United States, and societies of the south, like Brazil.

I. AN OVERVIEW OF INTELLECTUAL PROPERTY RULES/ LAWS AND WHAT IS CONSIDERED PATENTABLE

A. AN INTRODUCTION TO INTELLECTUAL PROPERTY RIGHTS—GENERAL, EVERYDAY IMPLICATIONS OF A PATENT AND THE PATENT PROCESS

Think of the infinite folklore associated with a four-leaf clover. Peoples' beliefs associated with the plant range from notions regarding its ability to bring good luck and even fortune, to its potential for fighting off evil spirits and witches.¹ Such beliefs date back to the middle ages.²

Now, imagine that growing up you had a childhood friend who truly believed clovers were in fact lucky, and, consequently, she would often gather wild clovers and rub them on her skin, believing such action helped ward off evil spirits and the infections and ailments those spirits might bring. Years later, you study microbiology as an undergraduate and upon graduation begin working at a pharmaceutical and chemical research company. Next, imagine you began experimentation with the red clover plant and discovered that extracting slaframine from diseased clover plants has medicinal effects linked to skin ailments such as eczema and psoriasis, in addition to showing signs of effectiveness in treating or even terminating cancers of the breast.³ As a result, your employer, the pharmaceutical company, patents the substance extracted from the clover as well as the process by which you extracted it. It stands to make millions of dollars once the newly found substance is made available in pill form and for sale on the market.

Should your friend be recognized in some way? Should she be entitled to share some portion of the profits that you and the pharmaceutical company stand to make from this discovery? Assuming you and your friend grew up in the United States, it is likely you both agree that she has no such right because even though your friend believed in the healing powers of the clover, she was not the individual or company that specifically identified her rights to those healing qualities by securing a patent.⁴

1. Healthy New Age, *Jewelweed and Benefits of Red Clover Leaf, Blossoms, and Tea*, <http://www.healthynewage.com/plant.html> (last visited Mar. 31, 2009).

2. *Id.*

3. *Id.*

4. World Intellectual Property Organization, *IP Services Frequently Asked Questions (FAQs)*, http://www.wipo.int/patentscope/en/patents_faq.html#inventions (last visited Mar. 31, 2009).

According to the World Intellectual Property Organization (WIPO), which is not simply a U.S. viewpoint, a patent secures an exclusive right for a person who creates an invention of either a product or a process that creates a new way of doing something or provides a new solution to a particular problem.⁵ And in U.S. culture, the concept that an individual will not receive credit for an idea alone is well known.⁶ Westernized societies, such as the United States, generally understand that a patent is secured only when something new is actually created, rather than when the idea for something is merely pondered or believed by an individual because that thought process only amounts to the potential for the creation of something new.⁷ Therefore, unless an individual has actually developed or created a new process based on an idea for a new or unique invention, he or she will not be entitled to any profits resulting from the sale of that creation. An idea alone is not sufficient.⁸

There is a generally accepted American concept that one does not receive credit for an accomplishment unless that credit is in a sense earned; this is why children are urged to work hard so their accomplishments may be recognized. So one might wonder why nearly every third grader in the United States would tell you that in 1492 Columbus sailed the ocean blue and discovered America. Because in reality, the commonly used rhyme is simply false: Columbus did not discover America; he landed in a land where he had never been and found an America that was already inhabited by numerous groups of indigenous societies including the Onondaga, the Lakota, and the Hopi.⁹

B. PATENTS AND PATENTABILITY IN THE UNITED STATES

In the United States, the U.S. Patent Act outlines that “whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof” is able to obtain a patent for that invention.¹⁰ Each word contained in the Patent Act has been subjected to further definition, and as a result, the term “process” has been considered the process or method by which an invention is produced, and “machine” is considered a mechanism that produces the invention or product.¹¹ In addition, the term “manufacture” refers to the creation of the invention itself, and “composition of matter” references the formula or composition required for an inven-

5. *Id.*

6. Maggie Kohls, *Blackbeard or Albert Schweitzer: Reconciling Biopiracy*, 6 CHI-KENT J. INTELL. PROP. 108, 108 (2007).

7. *Id.*

8. *Id.*

9. Robert Housman, *Sustainable Living: Seeking Instructions for the Future: Indigenous People's Traditions and Environmental Protection*, 3 TOURO J. TRANSNAT'L L. 141, 141 (1992).

10. 35 U.S.C. § 101 (1952).

11. Brian L. Smiler & Frederic H. Erbis, *Introduction to Intellectual Property, in INTELLECTUAL PROPERTY RIGHTS IN AGRICULTURAL BIOTECHNOLOGY* 9 (Frederic H. Erbis & Karim M. Mareid eds., 2d ed. 2004).

tion's existence.¹²

The U.S. Supreme Court decided to clarify the Patent Act's statutory language even further, particularly the term "manufacture" and the phrase "composition of matter," in the *Diamond v. Chakrabarty* (*Diamond*) case.¹³ The Court's interpretation of those particular phrases included a man-made bacterium that was a living microorganism.¹⁴ The unique living organism was created through genetic engineering processes and was useful because it was capable of breaking down crude oil.¹⁵ Thus, the new bacteria had utility, a characteristic that must be exhibited by an invention in order to be considered patentable.¹⁶ Regarding the invention's utility, the Court quoted Thomas Jefferson as inspiration for considering a living organism to be a patentable substance because Jefferson once stated, "ingenuity should receive a liberal encouragement."¹⁷

The interpretation adopted by the Supreme Court in *Diamond* helped update U.S. patent law alongside the enormous number of technological advancements taking place in scientific research by creating more far-reaching views as to what compositions of matter may appropriately be accepted in the patent process.¹⁸ *Diamond* "purportedly paved the legal way for the advent of patenting of genetically modified organisms," as well as "the rise of the biotechnology industry."¹⁹

Note, however, that despite the increasing realm of what would be considered patentable in the United States, there remain certain conditions and limitations related to patentability, and there is still the ability for one to lose the right to a patent.²⁰ An individual is not entitled to receive a patent in the United States if "the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent."²¹

Therefore, novelty remains a necessary requirement before an inven-

12. *Id.*

13. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

14. *Id.*

15. *Id.*

16. See 35 U.S.C. § 102(a) (1952).

17. *Diamond*, 447 U.S. at 309.

18. In terms of the patent application at issue, the Court in *Diamond* made a pioneering decision when a finding of non-patentability as to the living bacteria would have been far less controversial and far more easily justified. See Anna Lumelsky, *Diamond v. Chakrabarty: Gauging Congress' Response to Dynamic Statutory Interpretation by the Supreme Court*, Working Paper No. 288, BERKELEY ELECTRONIC PRESS, 2004, <http://law.bepress.com/cgi/viewcontent.cgi?article=1713&context=expresso>.

19. Valerie J. Phillips, *Half-Human Creatures, Plants & Indigenous Peoples: Musings on Ramifications of Western Notions of Intellectual Property and the Newman-Rifkin Attempt to Patent a Theoretical Half-Human Creature*, 21 SANTA CLARA COMPUTER & HIGH TECH. L.J. 383, 392 (2005).

20. 35 U.S.C. § 102(a).

21. *Id.*

tion warrants receiving a patent.²² In addition, an invention cannot be generally known or considered obvious to individuals in the inventor's field of skill.²³ The Supreme Court in the forward-looking, technology driven *Diamond* case noted that even though a living organism could potentially be considered patentable, because nature is something that is free to everyone, it may not be specifically reserved to anyone.²⁴ Nonetheless, the U.S. Board of Patent Appeals and Interferences of the U.S. Patent and Trademark Office has read the *Diamond* decision to mean that so long as a plant meets certain intellectual property requirements, any plant can in fact be patentable.²⁵

Related to the notion that some life forms are different from others and may simply be a part of nature, however, U.S. patent law specifically describes and limits the patentability of natural substances.²⁶ Per U.S. Patent Law, section 161, established in 1930, commonly referred to as the Plant Patent Act, a patent for plants was available to an individual who discovers and asexually reproduces a new, distinct plant variety that was not already in existence or previously cultivated.²⁷

On the one hand, this outlined limitations on plant patentability, but the Plant Patent Act also acknowledged acceptance of the idea that discovery could be "equated with invention, although the two words are hardly synonymous."²⁸ The acceptance of discovery in place of invention weakened the requirements outlined in the Patent Act and further expanded the realm of what can potentially be patented.²⁹ Additionally, by indicating that a plant need only be new and distinct in order to be patentable, the Plant Patent Act undermined additional requirements laid out in the Patent Act by eliminating the necessity that inventions have utility.³⁰ And finally, the Plant Patent Act also eliminated the Patent Act requirement that in order to be patented an invention must be capable of being described with a level of specificity that would allow others to reproduce it, thus making it easier for inventors and sellers of asexually reproduced plants to work with and patent plants. This once again showed the relaxed stance of U.S. patent law as it pertains to natural

22. Frederic H. Erbisich & Carlos Velazquez, *Introduction to Intellectual Property*, in *INTELLECTUAL PROPERTY RIGHTS IN AGRICULTURAL BIOTECHNOLOGY* 9 (Frederic H. Erbisich & Karim M. Maredia eds., 1998).

23. *Id.*

24. *Diamond*, 447 U.S. at 309.

25. John Barton, *Acquiring Protection for Improved Germplasm and Inbred Lines*, in *INTELLECTUAL PROPERTY RIGHTS IN AGRICULTURAL BIOTECHNOLOGY* 27-28 (Frederic H. Erbisich & Karim M. Maredia eds., 2d ed. 2004).

26. See 35 U.S.C. § 161 (2000).

27. In the United States, "Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state may obtain a patent therefore, subject to the conditions and requirements of this title." *Id.*

28. Phillips, *supra* note 19, at 395.

29. *Id.*

30. *Id.*

substances.³¹

Under the revised plant patent law set out in 7 U.S.C. § 2402, the U.S. view on plant patenting changed slightly by offering patent protection only for new, uniform, distinct, and stable discoveries.³² The “new” requirement means only that the plant variety was not previously sold and allows a one-year grace period for U.S. use and longer grace periods regarding foreign use.³³

To summarize the most recent view of plant patentability, in *Diamond*, patent rights related to plants were discussed as rights that were not aimed at allowing patentability for the recent discovery of plants or organisms already in existence within nature, but rather the decision allowed an individual who produced or created a new product or creation with the “aid of nature” to enjoy patent rights.³⁴ Thus, while bacteria may typically be considered a natural substance and therefore a part of nature, what distinguished the bacterium involved in *Diamond* was that it was unique from any bacteria already naturally occurring and readily accessible in nature.³⁵ Specifically, the new and unique bacterium in *Diamond* was identifiable and in existence because of the actions of its discoverer; his work resulted in the creation/discovery of a new bacterium with many valuable uses.³⁶ The Court’s decision was possible because the distinct requirement in U.S. patent law only requires that a plant variety be “clearly distinguishable from previous varieties,” which is “not as severe an inventive step requirement as is typical of patent law.”³⁷

II. CONCEPTS GENERALLY UNDERSTOOD BY AND NOTIONS/RULES APPLICABLE TO INDIVIDUALS IN THE UNITED STATES DO NOT ALWAYS EXTEND BEYOND AMERICA’S BORDERS—SO WHAT IS PATENTABLE IN THE REST OF THE WORLD?

A. THE WORLDLY VIEW: VARIOUS INTERNATIONAL ORGANIZATIONS’ PERSPECTIVE ON PATENTS AND PATENTABILITY

In establishing patent regimes in the midst of a biotechnology driven world, “[m]any scholars, activists, NGOs [non-governmental organizations], and international bodies. . . have made significant efforts to identify and articulate the indigenous viewpoint within the current globalizing

31. *Id.*

32. Barton, *supra* note 25, at 25-26; 7 U.S.C. § 2402 (1996).

33. *See* 7 U.S.C. § 2402.

34. *Diamond*, 447 U.S. at 312.

35. David B. Vogt, *Protecting Indigenous Knowledge in Latin America: Maintaining Biological Diversity, Creating Relationships, and Returning Benefits to Native Communities for Ethnobotanical Drug Discoveries—Can it be done?*, 3 OR. REV. INT’L L. 12, 24 (2001).

36. *Id.*

37. Barton, *supra* note 25, at 25.

trend of dominant intellectual property regimes.”³⁸

1. *World Intellectual Property Organization View*

The WIPO view regarding whether an invention is patentable has several requirements in order for patent protection to be granted.³⁹ An invention must be of PRACTICAL USE; must be novel by having a NEW CHARACTERISTIC that is not known in the EXISTING BODY OF KNOWLEDGE in the technical field related to the invention; and the invention must show innovation that could not be realized by an individual of average knowledge in that technical field.⁴⁰ Finally, the subject matter of the invention must be recognized as patentable under the applicable country’s law.⁴¹

Of particular importance is that the WIPO outlines that “in many countries, scientific theories, mathematical methods, plant or animal varieties, discoveries of natural substances, commercial methods, or methods for medical treatment (as opposed to medical products)” are generally not considered capable of securing patent protection.⁴² This acknowledgement is evidence of the WIPO’s efforts at remedying the challenges presented by the development and use of biotechnology and its overlap with indigenous knowledge, an area historically known as having little or no protection.⁴³ The WIPO viewpoint acknowledges that while the creation of new biotechnology may provide economic gain for its developers, those developers may not have any obligation to gain permission from originators or owners if that knowledge is considered traditional or indigenous knowledge.⁴⁴

2. *United Nations View*

Prior to the United Nations Conference on Environment and Development, held in Rio de Janeiro, Brazil in 1992, little attention was genuinely paid to the overlapping issues of intellectual property and biotechnology worldwide.⁴⁵ But all of that changed at the U.N. conference when the Convention on Biological Diversity (CBD) was established.⁴⁶ The CBD reflected the expanding international acceptance of the idea that every country, as well as every individual user/consumer of biological resources, has an interest and investment in maintaining the sustainability of such

38. IKECHI MGBEOJI, *GLOBAL BIOPIRACY PATENTS, PLANTS, AND INDIGENOUS KNOWLEDGE* 150 (W. Wesley Pue ed., UBC Press 2006).

39. *IP Services Frequently Asked Questions (FAQs)*, *supra* note 4.

40. *Id.*

41. *Id.*

42. *Id.*

43. Smiler & Erbis, *supra* note 11, at 14-15.

44. *Id.*

45. PADMASHREE GEHL SAMPATH, *REGULATING BIOPROSPECTING, INSTITUTIONS FOR DRUG RESEARCH, ACCESS AND BENEFIT-SHARING* 35 (United Nations University Press 2005).

46. Convention on Biological Diversity, June 5, 1992, 1760 U.N.T.S. 79, available at <http://www.cbd.int/doc/legal/cbd-un-en.pdf> [hereinafter CBD].

resources.⁴⁷ Nonetheless, the convention acknowledged that no one country or any particular user group has the best or perfect incentive for creating one internationally-focused solution capable of solving the varying global issues created by the worldwide use of biotechnology.⁴⁸

Currently, the CBD has 191 parties.⁴⁹ Among those who have signed on as parties to the convention are the United States and Brazil; however, the United States, unlike Brazil, is merely a signatory party to the convention and has not actually ratified the CBD.⁵⁰ Article 1 of the CBD outlines the three primary objectives encompassed within and strived for by the convention: "conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources."⁵¹

Numerous sections within the CBD are aimed at reinforcing the primary objectives of sustaining use and conservation of biotechnology, and there is also a strong focus on protection of traditional or local knowledge.⁵² Article 8(j) of the CBD deals with the recognition of traditional or indigenous knowledge when working to preserve biodiversity and requires that each "Contracting Party" shall:

respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.⁵³

Additionally, Article 15 recognizes national sovereignty rights applicable when a given genetic resource is located within a particular country's territory.⁵⁴ Finally, Article 16 addresses access to and transfer of technology and notes that if traditional knowledge were granted intellectual property rights, the access and transfer of such knowledge must "be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights."⁵⁵

47. SAMPATH, *supra* note 45, at 35.

48. *Id.*

49. Convention on Biological Diversity: List of Parties, <http://www.cbd.int/information/parties.shtml> (last visited Mar. 31, 2009).

50. *Id.*

51. CBD, *supra* note 46, at art 1. Article 2 of the CBD defines all of the relevant included terms and notes that "biotechnology" is "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use" "genetic resources," and also explains that "genetic material" is "any material of plant, animal, microbial or other origin containing functional units of heredity." *Id.* at art. 2.

52. See CBD, *supra* note 46.

53. *Id.* at art. 8(j).

54. *Id.* at art. 15.

55. *Id.* at art. 16(2).

The CBD perspective acknowledges that the issue must be evaluated in terms of both the conservation of natural substances and the use of those substances rather than simplifying the issue to only involve nature conservation.⁵⁶ Importantly, the CBD is distinguishable from previous international environmentally focused agreements due to the convention's acceptance of the fact that the only way to properly view the overlap between conservation and sustainable use of natural resources was to view biodiversity issues from within the international economic context.⁵⁷

3. *World Trade Organization View*

In 1995, the World Trade Organization (WTO) developed an agreement outlining Trade-Related aspects of Intellectual Property Rights, known as the TRIPS Agreement, which is a comprehensive multilateral agreement concerning intellectual property.⁵⁸ As laid out in its preamble, the TRIPS Agreement aims at attempting "to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade."⁵⁹ The primary objective of the TRIPS Agreement is to promote access to and the transfer of technological innovations, and, at the same time, balance the rights and obligations of those producing and using biotechnology against social and economic concerns.⁶⁰

Countries that sign the TRIPS Agreement agree to grant patents for any invention, both for products and processes, in all technology fields without discrimination, subject to standard requirements, including the requirements that the invention be novel and industrially applicable.⁶¹ In addition, the Agreement requires that patents and any accompanying rights be received without discrimination as to the invention's place of origin or whether the new product was locally produced or discovered.⁶²

There are, however, three listed exceptions to the TRIPS Agreement general rule regarding patentability.⁶³ The first exception applies to inventions that violate notions of public morality; specifically excluded are inventions dangerous to the life or health of humans, animals, plants, and

56. SAMPATH, *supra* note 45, at 35.

57. The CBD "mirrors the realization that biodiversity conservation is far more complex an issue than nature conservation and therefore entails taking into account a more offensive effort that tackles use and conservation of each component of biodiversity." *Id.*

58. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 33 I.L.M. 1981 (1994). *available at* http://www.wto.org/english/docs_e/legal_e/27-trips.pdf [hereinafter *TRIPS Agreement*].

59. *Id.* at Preamble.

60. *Id.* at art. 7.

61. World Trade Organization, *Overview: the TRIPS Agreement*, http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (last visited Mar. 31, 2009).

62. *Id.*

63. *Id.*

the environment.⁶⁴ The second exception is that diagnostic, therapeutic, and surgical methods for human or animal treatments may be excluded from being considered patentable per Article 27.3(a).⁶⁵

The final exception is especially relevant because it allows TRIPS member countries to effectively eliminate patents for certain substances by allowing countries to exclude from patentability “plants and animals other than microorganisms and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes[.]”⁶⁶ This ability, however, is limited by the TRIPS requirement that any country excluding patentability of plants must provide an effective *sui generis* system—meaning a system of its own—as a means of protection.⁶⁷

B. THE BRAZILIAN PERSPECTIVE: PATENTS/PATENTABILITY IN BRAZIL

In Brazil, from around 1970 through the 1980s, intellectual property law was not particularly well developed. Specifically, it did not provide for any sort of patent protection for pharmaceutical products or processes.⁶⁸ Currently, however, Brazilian intellectual property law is expanding. The major piece of legislation relating to intellectual property is Law 9.279—known as the Brazilian Patent Law.⁶⁹ The Brazilian Patent Law outlines a complete code for industrial property.⁷⁰ It establishes the rules for patents, protection for models of utility, industrial design, trademarks, geographic indications, and applicable time-limitations for each, as well as voluntary and required licenses, rights of the employers and employees, technology transfer and registry at the official agency, unfair competition, and describes potential available sanctions.⁷¹

For the most part, the framework of the Brazilian law falls within the general outline of the TRIPS Agreement. Yet in relation to the patentability of microorganisms, medicines, and chemicals, Brazilian patent law takes a different view than the standard views regarding patentability outlined in TRIPS.⁷² In fact, Brazilian patent regulations take a strong position and state that a patent is only granted for products manufactured

64. *Id.*

65. *TRIPS Agreement*, *supra* note 58, at art. 27.3(a).

66. *Id.* at art. 27.3(b).

67. *Id.*

68. Robert C. Bird & Daniel R. Cahoy, *The Emerging BRIC Economies: Lessons from Intellectual Property Negotiation and Enforcement*, 5 NW. J. TECH. & INTELL. PROP. 400, 412 (2007).

69. See Lei No. 9.279, de 14 de maio de 1996, 1 D.O., 15.05.1996 (Brazil), available at http://www.wipo.int/clea/en/text_html.jsp?land=EN&id.=515.

70. *See id.*

71. *Id.*

72. Francisco Eugenio Machado Arcanjo, *INTELLECTUAL PROPERTY RIGHTS AND BIODIVERSITY IN BRAZIL: CONSERVATION, SUSTAINABLE USE AND PROTECTION OF THE INDIGENOUS RIGHT* 11 (2000), <http://www.gwu.edu/~ibi/minerva/Fall2000/Eugenio.Arcanjo.pdf>.

in Brazil.⁷³ And per Article 68 of Law 9.279, if the product is not manufactured in Brazil three years after a patent is registered, the Brazilian government is authorized to issue a compulsory license for locally produced generic medicine.⁷⁴

This was an enormous change from the former state of intellectual property regulations in Brazil, which had been entirely lacking in the area of pharmaceutical product and processes patenting.⁷⁵ It is likely that this change was spurred by the Pharmaceutical Manufacturers' Association's allegation that Brazil's historically weak regulation of intellectual property and patents allowed for devaluation of Brazil's investments; decreased, or denied altogether, potential investment opportunities within Brazil; and interfered with exportation from Brazil, potentially amounting to losses in the hundreds of millions of dollars for the country.⁷⁶

In addition, another unique aspect of Brazilian patent law is that Brazil has concluded that certain microorganisms may not constitute inventions. Brazil has therefore labeled them unpatentable, including the whole or any portion of a living, natural organism, and any natural biological material (accessible in nature), even when such has been successfully isolated.⁷⁷ The limitation further includes the genomes or germplasms and any of the corresponding natural biological processes accompanying their production.⁷⁸

Brazil also restricts the patenting of transgenic microorganisms unless the organism displays a characteristic that is not typically displayed by the species under natural conditions.⁷⁹ Thus, in Brazil, a microorganism is potentially patentable but only if that microorganism has been successfully genetically modified.⁸⁰

Finally, specifically regarding plant patentability, Brazil has also adopted a Plant Variety (or Cultivar) Protection Law.⁸¹ According to the law, patents are available for both "novel plant" varieties, meaning that the "plant variety not having been offered for sale in Brazil for more than twelve months of the date of the application for protection. . .or offered

73. Lei No. 9.279 at art. 68.

74. *Id.*; Roger Bate & Richard Tren, *U.S., Brazil Dispute Patent Protection*, THE HEARTLAND INST., Mar. 1, 2006, <http://www.heartland.org/Article.cfm?artId=18587>.

75. See Bird & Cahoy, *supra* note 68, at 412.

76. *Id.* at 403.

77. Denis Borges Barbosa, *The New Brazilian Patent Law (1997)*, <http://denisbarbosa.addr.com/papers.htm> (follow "The New Brazilian Patent Law" hyperlink under "Papers in English").

78. *Id.*

79. John Tustin, *TRADITIONAL KNOWLEDGE AND INTELLECTUAL PROPERTY IN BRAZILIAN BIODIVERSITY LAW*, 14 TEX. INTELL. PROP. L.J. 131, 139 (2006).

80. Maria Jose Amstalden Sampaio, Margareth Maia de Rocha, & Elza Angela B. Brito da Cunha, *Exercising Intellectual Property Rights Management in Brazil: Research, Technology Transfer and Agribusiness After TRIPS*, in *INTELLECTUAL PROPERTY RIGHTS IN AGRICULTURAL BIOTECHNOLOGY* 289 (Frederic H. Erbsch & Karim M. Maredia eds., 2d ed. 2004).

81. Lei No. 9.456, de 4 de abril de 1997, 1 D.O. 25.04.1997. (Brazil), http://www.wipo.int/clea/docs_new/pdf/en/br/br005en.pdf.

for sale in other countries. . .for more than six years,” and for “distinct plant” varieties, which requires the plant be clearly new and distinguishable from any other plant already in existence on the patent application date.⁸²

III. DISTINCTIONS/DISAGREEMENTS BETWEEN U.S. AND BRAZILIAN INTELLECTUAL PROPERTY REGULATIONS AND THE ENSUING DISPUTES BETWEEN THE TWO COUNTRIES

A. U.S. VERSUS BRAZILIAN LAW

In beginning to examine U.S. views regarding patentability in relation to Brazilian views on basic patent law concepts and appropriate regulations, the idea that theories of nature, physical phenomenon, and substances naturally occurring in nature are not things considered patentable—which was articulated by the U.S. Supreme Court in *Diamond*⁸³—seems rather consistent with Brazilian intellectual property theories on the non-patentability of microorganisms and the categorization of such as non-inventions.⁸⁴ But as further analysis has revealed, in the United States a natural substance may nonetheless be considered patentable if that substance is processed and/or refined to create what constitutes a new product or process.⁸⁵

Unlike in Brazil, a substance can therefore be considered patentable in the United States even if it is derived from nature if the substance has been refined.⁸⁶ Also contrary to Brazilian patent law restrictions, the U.S. Patent and Trademark Office (PTO) has allowed issuance of patents for genes and genomes, relying on the notion that an isolated gene's chemical structure is unique from the same gene when it is found within a living organism.⁸⁷ This includes issuance of patents for DNA so long as that particular DNA has been isolated or purified.⁸⁸ Finally, U.S. law allows for the patenting of transgenic microorganisms when the organism has been successfully engineered by an individual, a far less demanding requirement than that applied in Brazil.⁸⁹

Brazil, on the other hand, does not allow a patent to be issued for organisms, microorganisms, or any biological matter located in nature.⁹⁰ This exclusion from patentability includes both germplasms as well as ge-

82. *Id.* at tit. 2, paras. 5, 6.

83. *Diamond*, 447 U.S. at 309.

84. See Sampaio, Rocha, & Cunha *supra* note 80, at 289.

85. In, *Parke-Davis v. Mulford*, the oldest cited U.S. case with regard to patentability of natural substances, the patent applicant was successfully able to patent adrenalin. *Parke-Davis v. H.K. Mulford Co.*, 189 F. 95, 103 (C.C.S.D.N.Y. 1911).

86. *Id.*

87. In a relatively recent case, an anonymous patent applicant attempted to patent a DNA sequence coding for human tissue, but was ultimately unsuccessful because the DNA sequence, while coded, was not successfully isolated. *Ex Parte D*, 27 U.S.P.Q. 2d 1067 (1993).

88. *Id.*

89. *Diamond*, 447 U.S. at 309-10.

90. Lei No. 9.279 at art. 10.

nomes.⁹¹ Brazil also expressly prohibits issuance of patents for any substance produced from a living organism; it has established a prohibition against patenting transgenic microorganisms that do not meet the specified requirements for patentability—novelty, industrial application, and inventive activity.⁹² And finally, Brazil only allows for the patenting of transgenic microorganisms if the organism develops a characteristic not typically displayed by the organism's species under natural conditions.⁹³

1. *Plant Patents—Common Ground between U.S. and Brazilian Patent Law*

Plant patenting is an important area in intellectual property and an important part of ensuing debates regarding what exactly may be patentable.⁹⁴ Because neither the United States nor Brazil allows for the patenting of entire organisms, with the exception of transgenic microorganisms, "plant patents fill the void made necessary by valuable plant hybrids and transgenic plants by offering less than full patent protection[.]"⁹⁵ And on the subject of plant patentability, the plant application procedures in both countries are identical, displaying at least one common thread between these two countries' viewpoints and regulations regarding patents and patentability.⁹⁶

B. THE UNITED STATES VERSUS BRAZIL—A RECURRING TREND IN THE INTELLECTUAL PROPERTY ARENA

The Pharmaceutical Manufacturers' Association's conclusions regarding the weak status of Brazil's intellectual property and patent laws, discussed above, not only led to a reformation in Brazilian law, it also instigated a vigorous dispute between the United States and Brazil on the subject of patent protections in the late 1980s.⁹⁷ The association lodged a petition with the United States Trade Representative (USTR) alleging unfair trade practices relative to certain products and processes.⁹⁸ This ultimately led to President Reagan's imposition of a significant tariff on Brazilian imports to the United States.⁹⁹ A resolution did not come, and the United States did not remove the tariff or its trade sanctions imposed against Brazil until after the Brazilian government announced its plan to implement legislation that would serve to protect pharmaceutical prod-

91. *Id.*

92. *Id.* at art. 18.

93. *Id.*

94. Tustin, *supra* note 79, at 139.

95. *Id.*

96. In both the United States and Brazil, a patent application for a plant patent requires specific of the individual who improved or enhanced the plant sample in some way, regardless of whether or not a company is the patent applicant. *Id.*

97. Bird & Cahoy, *supra* note 68, at 12.

98. *Id.*

99. *Id.*

ucts and processes.¹⁰⁰

In 2001, the USTR again became involved in what would amount to a heated disagreement between the United States and Brazil regarding intellectual property and trade policies when it expressed opinions stating that certain provisions within Brazil's patent law were in direct conflict with portions of the TRIPS Agreement,¹⁰¹ including TRIPS Article 27.1, which states:

[P]atents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. . . patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.¹⁰²

And according to the USTR, Brazilian law was also in conflict with Article 28.1 of the TRIPS Agreement, which outlines the rights applicable to the holder of a patent for either a product or a process.¹⁰³

The conflict was particularly based on the idea that those articles expressly prohibit discrimination in granting patent protection and expressly require exclusivity in the rights of a patent holder,¹⁰⁴ two concepts that seem inconsistent with the requirements outlined in Brazilian law, particularly Article 68 of the Brazilian Patent Law.¹⁰⁵ Article 68 would allow the Brazilian government the ability to issue a compulsory license requiring local generic production of a product if the product, once granted a patent, was not manufactured in Brazilian territory within three years of the issuance of the patent.¹⁰⁶

The conflict or inconsistency alleged was relevant because Brazil adopted the TRIPS agreement in 1997, which was years prior to its being required to do so.¹⁰⁷ Nevertheless, Brazil decided to adopt and implement the TRIPS regulation more than three years prior to the deadline for developing countries.¹⁰⁸ The problem with its implementation of TRIPS was that in addition to that agreement, Brazil still maintained its own patent regulation.¹⁰⁹ This regulation provided that a patent would only be granted on products that were manufactured in Brazil, and as outlined above, that law was arguably contrary to the regulations outlined in the TRIPS Agreement.¹¹⁰

100. Determination to Terminate Increased Duties on Certain Articles from Brazil, 55 Fed. Reg. 27,324-02 (July 2, 1990).

101. Bate & Tren, *supra* note 74.

102. *TRIPS Agreement*, *supra* note 58, at art. 27.1

103. *Id.* at art. 28.1.

104. Bate & Tren, *supra* note 74.

105. Lei No. 9.279 at art. 68.

106. *Id.*

107. *TRIPS Agreement*, *supra* note 58, at art. 65.

108. *See id.*; *see also* Bate & Tren, *supra* note 74.

109. Bate & Tren, *supra* note 74.

110. *Id.*

The United States initially attempted to clarify and resolve its dispute regarding the conflict between Brazilian law and the TRIPS Agreement through the WTO by filing a complaint against Brazil.¹¹¹ Later, however, the United States withdrew its complaint based on an agreement made with the Brazilian government.¹¹² Both the United States and Brazil decided that use of the U.S.-Brazil Consultative Mechanism would be more appropriate.¹¹³ According to then-U.S. Trade Representative (USTR) Robert Zoellick, the United States and Brazil needed to work together to search out and hopefully achieve some innovative solutions.¹¹⁴

Nonetheless, another statement by Zoellick, on behalf of the U.S. government, reiterated that even though solutions were being sought out, the USTR still strongly stood behind its position.¹¹⁵ Namely, Brazil's requirement of local manufacturing as a condition before it would issue patent protection was "inimical to the principles of free trade and inconsistent with various WTO rules, including the TRIPS Agreement."¹¹⁶ He urged that, in the future, the U.S. government would still "aggressively engage other countries that impose or maintain such requirements and, if appropriate, pursue WTO dispute settlement."¹¹⁷

On the other hand, the Brazilian ambassador to the WTO, Celso Amormim, actually issued a warning regarding U.S. opposition to Article 68 of Patent Law 9.279.¹¹⁸ He claimed that U.S. accusations were legally unfounded and threatened that they may also "prove politically disastrous."¹¹⁹ Indeed, there has been intense political pressure against the United States and in support of Brazil, and numerous activist groups have likewise come out in support of Brazil and in opposition to the United States.¹²⁰

One such group is the globally recognized and Nobel prize-winning association Doctors Without Borders.¹²¹ The organization has gone on record to argue that the U.S. challenge may have globally harmful effects

111. SAMPATH, *supra* note 45, at 42, 58 n.12.

112. *Id.*

113. Bate & Tren, *supra* note 74.

114. *Id.*

115. Gavin G. Yerkey & Daniel Pruzin, *United States Drops WTO Case Against Brazil Over HIV/AIDS Patent Law*, *WTO Rep., Bureau of National Affairs* (June 26, 2001), at <http://www.cptech.org/ip/health/c/brazil/bna06262001.html>; see also Press Release, U.S. Trade Representative [USTR], United States and Brazil Agree to Use Newly Created Consultative Mechanism to Promote Cooperation on HIV/AIDS and Address WTO Patent Dispute (June 25, 2001), available at http://www.ustr.gov/Document_Library/Press_Releases/2001/June/United_States_Brazil_agree_to_use_newly_created_Consultative_Mechanism_to_promote_cooperation_on_HIV-AIDS_address_WTO_p.html?ht= [hereinafter USTR Press Release (June 25, 2001)].

116. Yerkey & Pruzin, *supra* note 115; see also USTR Press Release (June 25, 2001), *supra* note 115.

117. Yerkey & Pruzin, *supra* note 115; see also USTR Press Release (June 25, 2001), *supra* note 115.

118. Bate & Tren, *supra* note 74.

119. *Id.*

120. *Id.*

121. Yerkey & Pruzin, *supra* note 115.

by potentially handicapping “the successful Brazilian AIDS program, which is largely based on Brazil’s ability to manufacture affordable treatment. . . [because] [t]he Brazilian patent policy has been key to the success of the strategies to offer universal access to HIV/AIDS medication in Brazil.”¹²²

Despite Brazil’s strengthening voice in intellectual property disputes, the United States, via the USTR, has had a commanding role in working toward the expansion of patent laws worldwide. Specifically, the USTR monitors the efforts of other governments, including Brazil, to gauge the effectiveness and ability of their actions to protect intellectual property rights.¹²³ Brazil’s efforts, and its increasingly strong position on intellectual property issues, have not gone unnoticed however, as the country was lowered from the USTR’s “Priority Watch List” to the “Watch List” in the annual 2007 USTR Special 301 Report.¹²⁴ The decision to decrease Brazil’s priority level takes into consideration the country’s nationwide action plan outlining piracy and intellectual property crimes, as well as the effectiveness of Brazil’s National Anti-Piracy Council, an efficient model for dealing with the overlap of public and private activities in the intellectual property arena.¹²⁵

Nevertheless, the USTR outlines numerous remaining problems the United States sees regarding Brazilian patent law, including an argument that Brazil still lacks an efficient system for dealing with patent applications.¹²⁶ In addition, the USTR expressed concern about the undefined role of Brazil’s health regulatory agency in the decision process for issuance of patents.¹²⁷ On that topic, Brazil has on some occasions indicated that it was considering the use of compulsory licensing for the patenting of pharmaceutical products.¹²⁸ In response, the United States emphasized the need for Brazil to engage in open-ended and completely straightforward discussions with all interested parties related to the issuance of patents, so that all involved will be able to reach what each considers mutually satisfactory outcomes.¹²⁹ Thus, despite noticeable progress between the United States and Brazil in the debate on intellectual property, the United States remains concerned about Brazil’s patent

122. *Id.*

123. *See generally* Office of the United States Trade Representative, *Mission of the USTR*, http://www.ustr.gov/Who_We_Are/Mission_of_the_USTR.html (last visited Apr. 13, 2009).

124. U.S. TRADE REPRESENTATIVE, 2007 SPECIAL 301 REPORT 3 (2007), http://www.ustr.gov/assets/Document_Library/Reports_Publications/2007/2007_Special_301_Review/asset_upload_file230_11122.pdf.

125. *Id.* at 30. The USTR Watch List outlines that “[w]hile piracy and counterfeiting still exist at high levels and criminal prosecutions often lag police actions, Brazil merits recognition for its vigorous efforts. The United States looks forward to a continued healthy dialogue with Brazil on IP issues, including through the U.S.–Brazil Bilateral Consultative Mechanism and the U.S.–Brazil Commercial Dialogue.” *Id.*

126. *Id.*

127. *Id.*

128. *Id.*

129. *Id.*

system and is still engaged in efforts aimed at trying to reform that system.¹³⁰

IV. THE BIOPROSPECTING/BIOPIRACY DICHOTOMY AND THE IMPACT OF BRAZIL'S AND THE UNITED STATES' DIFFERING STANDARDS REGARDING PATENTS AND PATENTABILITY ON EACH COUNTRY'S VIEWPOINT IN THE DEBATE

Biodiversity is typically associated with a specific location, and the world's tropics, which are home to unique and magnificent ecosystems, encompass a predominate percentage of the world's biodiversity.¹³¹ Biodiversity is often characterized as a common resource exhibited and shared by a locality.¹³² Commentators have noted, however, that "the emergence of new intellectual property regimes, and new and accelerated potential for exploitation of biodiversity, creates new conflicts over biodiversity—between private and common ownership, between global and local use."¹³³ Biodiversity has, in a way, become a raw material or commodity, and access to it (and its transfer beyond its native localities) has created a heated debate regarding what is the appropriate treatment of biodiversity and biotechnology.¹³⁴

A. THE BIOPROSPECTING PERSPECTIVE

The "bioprospecting" perspective views researchers as having the potential to locate and use valuable resources and knowledge not available outside of indigenous cultures and lands.¹³⁵ It argues that all three of the CBD's objectives—sustainable use, conservation of biological resources, and benefit sharing—can effectively be met through proper bioprospection.¹³⁶ Bioprospecting is a means to retrieve and generate both products and revenue through the use of biological resources and traditional knowledge that would otherwise likely remain undeveloped in many localities.¹³⁷

Under this perspective, "bioprospectors" are scientists or researchers who search any and all areas of the world, with the goal of locating substances which are already known, or discovering new substances.¹³⁸ According to the bioprospecting perspective, new substances discovered and retrieved from the plants and/or animals inhabiting exotic locales will al-

130. *See id.*

131. *See* VANDANA SHIVA, *BIOPIRACY: THE PLUNDER OF NATURE AND KNOWLEDGE* 65-67 (1997). The tropics are primarily located in third world countries, which are "endowed with this wealth of biological diversity." *Id.* at 65.

132. *Id.* at 67.

133. *Id.* at 66.

134. *See id.*

135. SAMPATH, *supra* note 45, at 5.

136. *Id.*

137. *Id.*

138. Kohls, *supra* note 6, at 108.

low for the creation of valuable new drugs or new food sources.¹³⁹

The exploration is often dangerous, however, as the locations are remote and treacherous, and the researchers have no guarantees regarding their searches or subsequent research.¹⁴⁰ As a result, the bioprospector gambles both the loss of his safety and his resources in order to explore and potentially make a discovery.¹⁴¹ From such a perspective, it is easy to see how some view these researchers as “modern day heroes, facing danger and financial loss in hopes of finding new cures and new crops for humanity.”¹⁴²

B. THE BIOPIRACY PERSPECTIVE

While the bioprospecting perspective views researchers as valiant explorers searching for new sources of medicine and foodstuff, many others take a different view and consider numerous scientists and researchers to be biopirates rather than bioprospectors.¹⁴³ According to the biopiracy viewpoint, “biopirates” are performing “biopiracy”—the theft of natural and biological resources from their natural habitat and using such for commercial profit.¹⁴⁴

Such thievery is viewed as being performed at the expense of the country where the substance was discovered in nature.¹⁴⁵ Under the biopiracy perspective, it is suggested that biodiversity belongs to indigenous cultures. Biopiracy, therefore, is “a process by which the rights of indigenous cultures to their genetic resources and associated traditional knowledge are replaced by monopoly rights of those who exploit these resources.”¹⁴⁶

Those who consider explorations and discoveries to be theft have argued that western corporations are willing to explore the most remote areas of the world in hopes of finding and taking materials and substances that actually belong to the indigenous peoples of those lands.¹⁴⁷ Critics have used flamboyant phrases like “biological colonialism,” “genetic imperialism,” and “plunder” to narrate and describe their view of what a biopirate researcher is ultimately accomplishing.¹⁴⁸ Ultimately, the biopiracy perspective is rooted in larger concerns of neoimperialism, whereby a westernized nation or group is able to completely “usurp” another nation’s resources and exploit the knowledge of that country’s in-

139. *Id.*

140. *Id.*

141. *Id.*

142. *Id.*

143. *Id.*

144. Paulo Prada, *Poisonous Tree Frog Could Bring Wealth to Tribe in Brazilian Amazon*, N.Y. TIMES, May 30, 2006, at C1, available at <http://www.nytimes.com/2006/05/30/business/worldbusiness/30frogs.html>.

145. *Id.*

146. SAMPATH, *supra* note 45, at 5.

147. See generally Jim Chen, *There’s No Such Thing as Biopiracy. . .and It’s a Good Thing Too*, 37 MCGEORGE L. REV. 1, 1-4 (2006).

148. *Id.* at 4.

digenous peoples.¹⁴⁹

C. U.S. AND BRAZILIAN VIEWPOINTS IN THE BIOPIRACY VERSUS BIOPROSPECTING DEBATE

Not surprisingly, these opposing perspectives on making use of biodiversity have been the source of tension. A recent *New York Times* article illustrated the severe actions and implications that can accompany scientific research when the fruits of that research raise intellectual property concerns.¹⁵⁰ The article cites the example of Marc van Roosmalen, a respected and well known primatologist, whose Amazonian research had previously led to the discovery of five different monkey species as well as a new genus of primates.¹⁵¹ In the course of his research, Mr. van Roosmalen was faced with allegations of biopiracy and ultimately sentenced to almost sixteen years in prison in Brazil.¹⁵²

1. *The View of Brazil and Other Undeveloped Countries*

Brazil, like other developing nations, is a leader among those attempting to fight back against biopiracy and has the goal of stopping what it considers theft of its biological resources.¹⁵³ The recent sentencing of Marc van Roosmalen shows just how serious the country is about protecting its natural resources.¹⁵⁴ Representatives from the Brazilian government stress that there is no national vendetta against scientists conducting research in Brazil, suggesting instead that the country is simply trying to protect its "natural and genetic patrimony."¹⁵⁵

Brazil, along with many other developing countries whose lands are rich with biodiversity, also has good reason to fear the unauthorized taking of any of its genetic resources.¹⁵⁶ Brazil is not only the recent target of western corporations' research and exploration, the country also has had a history of experiences with biopiracy, including its most infamous example involving the Amazonian rubber tree.¹⁵⁷

Amazonian rubber trees were the primary production source for natural rubber in the mid-nineteenth century.¹⁵⁸ During that time, the demand for rubber, as well as rubber prices, exploded because of the start of the industrial revolution in North America and Europe.¹⁵⁹ The subsequent rubber boom in Brazil, however, and the country's lucrative mo-

149. SAMPATH, *supra* note 45, at 5.

150. See Larry Rohter, *As Brazil Defends Its Bounty, Rules Ensnare Scientists*, N.Y. TIMES, Aug. 28, 2007, at F1, available at <http://www.nytimes.com/2007/08/28/science/28biop.html>.

151. *Id.*

152. *Id.*

153. Prada, *supra* note 144.

154. Rohter, *supra* note 150.

155. *Id.*

156. See Tustin, *supra* note 79, at 133-34.

157. *Id.*

158. *Id.*

159. *Id.* at 133.

nopoly over production of the product, quickly disappeared after Sir Henry Wickham, a British explorer and botanist, located and removed rubber seeds from Brazil and began producing rubber elsewhere until rubber flooded the international market.¹⁶⁰

Another example of what Brazil considers biopiracy of its resources occurred in the 1970s, when a pharmaceutical company researched a Brazilian arrowhead viper and subsequently extracted the snake's venom that it used to develop captopril, a drug used for hypertension and congestive heart failure treatments.¹⁶¹ At the time, Brazil argued it was entitled to royalty payments based on the company's use of the Brazilian resource, but the company never submitted to Brazil's request for acknowledgement.¹⁶²

Brazil's experiences, and the refusal by others to recognize its claims of biopiracy, have led to its expanding of laws and regulations dealing with patents, patentability, and intellectual property in an attempt to solve future problems with biopiracy.¹⁶³ In addition to taking regulatory measures, Brazil has also asserted its position against biopiracy by taking a more proactive role in exploring development of its own resources in order to ensure proper acknowledgement and potential profits from another's use of the country's indigenous resources or knowledge.¹⁶⁴ Brazil's proactive approach is evidenced by the government's recent promotion of national research in order to determine if a traditional belief regarding the healing qualities of an Amazonian frog's "slime" are correct—a determination that may lead to the nation's own advancement in pharmaceutical research and development.¹⁶⁵ Brazil's efforts coincide with the attempts by many developing countries striving for their own development and commercialization of traditional medicines and local resources in the local setting to prevent foreigners' exploitation of their local knowledge and resources.¹⁶⁶

In addition to its expanding use of patent and intellectual property laws, Brazil, and many other developing countries, has come out in favor of the CBD because its approach regarding patents allows the locality where a new product is produced to take steps to protect its own natural resources and indigenous knowledge.¹⁶⁷ Brazil has urged countries

160. *Id.* at 133-34; *see also* Rohter, *supra* note 150.

161. Rohter, *supra* note 150.

162. *Id.* Also, in a less specific example of alleged biopiracy, Brazilian Indian tribes recently reported that "samples of their blood, taken under circumstances they say were unethical, were being used in genetic research around the world."

163. *See id.*

164. *See* Prada, *supra* note 144.

165. *Id.* The Brazilian government has wholeheartedly backed Fernando Katukina, the chief of an indigenous tribe in the Amazon, who believes that his tribe's traditional knowledge relating to the power of a frog's slime to both anesthetize and tranquilize, by promoting Brazilian research of the slime's potential.

166. *Id.*

167. *See* Kirit K. Patel, *Farmers' Rights Over Plant Genetic Resources in the South: Challenges and Opportunities*, in *INTELLECTUAL PROPERTY RIGHTS IN AGRICULTURAL BIOTECHNOLOGY* 95, 103 (F.H. Erbsch & K.M. Maredia eds., 2d ed. 2004).

worldwide to acknowledge the superior status of the CBD, “which essentially implies that every patent application based on genetic material or an associated local knowledge system has to ensure that the patentee has acquired the genetic material legally and with the prior informed consent of the original owner of that particular material.”¹⁶⁸

2. *The View of the United States and Other Industrialized Nations*

Westernized societies such as the United States, on the other hand, typically favor the TRIPS Agreement and consider it a sufficient regime for both regulating international trade of intellectual property and protecting against biopiracy.¹⁶⁹ Industrialized nations have demanded that TRIPS take priority over the CBD and other agreements as the dominant international agreement on intellectual property.¹⁷⁰

The TRIPS Agreement was modeled to promote prosperity worldwide by implementing free trade, internationally free flowing capital markets, and strong protections for intellectual property.¹⁷¹ As a result of its strong focus on the promotion of international trade and open capital markets, and its similarities to the U.S. patent regime, TRIPS has often been considered the “American model” for governing intellectual property at the international level.¹⁷² Thus, it is no coincidence the United States and other westernized societies strongly support the TRIPS Agreement.¹⁷³

Industrialized nations have not only pushed for TRIPS to take priority over the CBD, but many have come out in opposition of Article 27.3 of the TRIPS Agreement, the one portion of the agreement that was reflective of the CBD’s focus on national sovereignty on patent rights.¹⁷⁴ Such nations have suggested revision of Article 27.3 because they argue it currently offers too much leverage to countries to vary the intellectual property regime and create their own set of rules by allowing individual countries to place restrictions on the patentability of plants and other living organisms.¹⁷⁵

This is an extremely strong position because Article 27.3 of TRIPS has been considered the primary way of ensuring that traditional knowledge be potentially recognized and the appropriate accompanying rights granted to the countries in possession of that knowledge.¹⁷⁶ It is considered the only TRIPS provision that is more “equitable from the perspective of developing countries.” Therefore, its revision or elimination

168. *Id.*

169. *See id.*

170. *Id.* at 103-04.

171. Steve Lohr, *Debate on Intellectual Property*, N.Y. TIMES, Oct. 14, 2002, <http://www.nytimes.com/2002/10/14/technology/14NECO.html>.

172. *Id.*

173. *See id.*

174. *See Patel, supra* note 167, at 103-4.

175. *Id.*

176. SAMPATH, *supra* note 45, at 46.

would result in almost no protection for developing countries and almost certain failure for any country's attempts at protecting its indigenous knowledge and resources.¹⁷⁷

Despite certain industrialized nations seeking even fewer protections for developing countries' own patent protections and therefore even greater free trade than what results from the TRIPS Agreement, many economists already consider TRIPS to be a massive victory for industrialized nations, including the United States and many U.S. industries.¹⁷⁸ According to economists, the agreement is considered an enormous win within a few specific industries, including the pharmaceutical industry and software industry because of the substantial profits gained in those industries based on TRIPS protections.¹⁷⁹ One expert on trade relations suggests that "TRIPS was a matter of powerful companies with intellectual property concerns essentially dictating trade policy."¹⁸⁰

As a result of the stronger intellectual property protections provided for under the TRIPS Agreement and the similarities of the agreement's position on patent systems to the United States' own patent system, the United States stands to benefit from TRIPS more than any other country.¹⁸¹ One study estimates "American companies would pocket an additional \$19 billion a year in royalties, while developing nations like China, Mexico, Brazil, and India—net importers of intellectual property—would pay more to the patent holders" following implementation of the TRIPS Agreement internationally.¹⁸² Accordingly, U.S. courts are known as proponents of industry interests, in that they nearly always prevent the "infringing of patents with exorbitant penalties" and thereby safeguard the interests of industry.¹⁸³

Many scientists and researchers have opinions close to the viewpoints expressed by industrialized nations in that they are wary of individual countries' actions at protecting local intellectual property rights.¹⁸⁴ Researchers have argued that developing countries that impose strict regulations on patenting and unclear guidelines for research in an attempt to strenuously object to and prevent biopiracy are actually harming the scientific field.¹⁸⁵ They claim that patent regulation aimed at protecting indigenous resources and knowledge is the work of "overzealous bureaucrats" and is often so restrictive that it has criminalized research and created "paranoia and a disaster for science" when research should be encouraged.¹⁸⁶

177. *Id.*

178. Lohr, *supra* note 171.

179. The pharmaceutical and software industries "interests were championed by the United States government." *Id.*

180. *Id.*

181. *Id.*

182. *Id.*

183. Patel, *supra* note 167, at 102.

184. See Rohrer, *supra* note 150.

185. *Id.*

186. *Id.*

V. CONCLUSIONS—WHAT IS THE BEST INTERNATIONAL SYSTEM FOR PROTECTION OF INTELLECTUAL PROPERTY? AND WHAT'S NEXT REGARDING BIOPIRACY/BIOPROSPECTING?

While the TRIPS Agreement and the CBD are very different, and their differences are often contrasted, there is no direct legal divergence between the two agreements.¹⁸⁷ Nevertheless, the CBD has a strong focus on the “fair and equitable sharing of benefits arising out of the commercialization of biological resources”¹⁸⁸ and is adamant about enforcing such.¹⁸⁹ To provide for this sharing, the CBD recognizes a certain level of national sovereignty in dealing with the regulation of the indigenous natural substances located and then discovered within a particular country. In contrast, “the overriding nature of the TRIPS Agreement would hardly have provided a way out for developing countries to coin restrictions on use of traditional knowledge.”¹⁹⁰

A. WHAT'S BEST?

Industrialized nations today, like the United States in the nineteenth century during the industrial revolution, are all too often pirates of developing countries' intellectual property.¹⁹¹ And the potential harms associated with biopiracy or bioprospection, regardless of what the practice is labeled, are too severe to ignore the necessity for indigenous knowledge and indigenous resource protection.¹⁹²

Biopiracy places indigenous resources and traditional knowledge at risk of exploitation, but an even greater risk is posed to the people and cultures that hold such knowledge.¹⁹³ Indigenous societies are threatened with destruction.¹⁹⁴ Anthropological estimates outline that nearly eighty-five Brazilian Indian groups became extinct between 1900 and 1950.¹⁹⁵ “Destruction of ecosystems in search for expanded agricultural lands, deforestation associated with harvesting of timber and other forest products, and appropriation of traditional knowledge with no rewards to the holders of that knowledge” all attributed to the destruction of those peoples and their knowledge.¹⁹⁶

187. SAMPATH, *supra* note 45, at 44.

188. CBD, *supra* note 46, at art. 1.

189. *Id.* at art. 15; SAMPATH, *supra* note 45, at 36.

190. SAMPATH, *supra* note 45 at 44-5.

191. *See* Lohr, *supra* note 163. “But these days, when it comes to dealing with developing nations around the world, the United States seems to be ignoring its own swashbuckling heritage.” *Id.*

192. John Mugabe, *Intellectual Property Protection and Traditional Knowledge, An Exploration in International Policy Discourse*, WIPO Panel Discussions, <http://www.wipo.int/tk/en/hr/paneldiscussion/papers/pdf/mugabe.pdf> (last visited Apr. 13, 2009).

193. *Id.*

194. *Id.*

195. *Id.*

196. *Id.*

The TRIPS Agreement contains a built-in bias toward traditional knowledge and does not provide for its protection.¹⁹⁷ Under TRIPS, there is no effective protection of the rights of communities because the agreement provides no guarantee that those groups will be given control over their own natural resources and the patenting and development of such.¹⁹⁸ The rights of a group of indigenous people who have maintained a particular resource or developed particular traditional knowledge for thousands of years, will not be recognized as having ownership of those resources under the TRIPS Agreement.¹⁹⁹ This has allowed for companies that develop traditional resources or knowledge to use TRIPS to their advantage and maximize their own profits at the expense of developing countries and their indigenous peoples.²⁰⁰ Thus, because TRIPS is ineffective in allowing developing countries and indigenous cultures to protect their resources against biopiracy and the potentially devastating consequences of biopiracy, the TRIPS Agreement alone is not a sufficient international model for protecting intellectual property rights.²⁰¹

The TRIPS Agreement should therefore be modified so that it reflects some basic principles protecting indigenous knowledge and resources, like the protections outlined in the CBD.²⁰² The CBD was written with a major objective being to prevent the theft of indigenous knowledge. And while the current relationship between TRIPS and the CBD remains unclear, in the future the CBD's biopiracy prevention objectives should be adopted within the TRIPS Agreements trade objectives.²⁰³ "Removing the inconsistencies between TRIPS and CBD should be an important part of the international campaign for the review and amendment of TRIPS."²⁰⁴

The CBD is an effective international framework on intellectual property and should serve as a model for other such agreements because it offers "a comprehensive cross-sectoral approach to biodiversity conservation that seeks to integrate use with incentives to conserve, from a global to a local level."²⁰⁵ Local needs must be recognized in any effective global biodiversity policy.²⁰⁶

In addition to protecting localities, it is argued that the protection of traditional knowledge aspects of intellectual property, like that outlined

197. See SAMPATH, *supra* note 45, at 44-5.

198. Rangarirai Machemedze, *Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) Overview*, SEATINI, (2003), <http://www.seatini.org/publications/factsheets/trips.htm>.

199. *Id.*

200. *See id.*

201. SAMPATH, *supra* note 45, at 44-5.

202. *See id.*

203. *See* Mugabe, *supra* note 192.

204. Vandana Shiva, *The U.S. Patent System Legalizes Theft and Biopiracy*, THE HINDU, July 28, 1999, <http://www.organicconsumers.org/Patent/uspatsys.cfm>. "The implementation of TRIPS, which is based on the U.S. style patent regimes, should be immediately stopped and its review started." *Id.*

205. SAMPATH, *supra* note 45, at 35.

206. *See id.* at 38.

in the CBD, can actually help promote technological innovations by facilitating “the dissemination and development of that knowledge in the modern economic space.”²⁰⁷ Additionally, recognizing and proper protection for traditional knowledge and resources might also create incentives among developing countries and their indigenous inhabitants to become involved in environmental conservation and the management and preservation of biodiversity.²⁰⁸ Finally, implementation of the CBD’s requirements regarding fair and equitable sharing of benefits would require industrialized countries to adopt a moral obligation to localities requiring the countries to respect the true discoverers and users of traditional knowledge and resources before allowing for commercialization of such resources.²⁰⁹

B. WHAT’S NEXT?

In considering the likelihood of whether or not CBD-like changes or amendments will be made to the TRIPS Agreement and whether the CBD can therefore become more effective in promoting the protection of indigenous knowledge in the future, it is important to return to the 2001 heated dispute between the United States and Brazil, discussed earlier.²¹⁰ That conflict was in regard to the TRIPS Agreement’s conflict with the Brazilian patent law that allowed Brazil to have control over the use of its indigenous resources based on the law’s compulsory licensing for local production within Brazil.²¹¹ The result of the Brazilian law was increased Brazilian protection of its natural resources as well as increased Brazilian production of drugs.²¹²

While in that dispute, Brazil did not back down despite the “the economic and political influence of the United States over global intellectual property law,”²¹³ the debate was never fully or officially resolved in Brazil’s favor. Likewise, the ability of TRIPS to trump local regulation of indigenous resources was never critically examined because the United States withdrew its formal complaint.²¹⁴

The U.S. withdrawal came because the ultimate effect of the Brazilian compulsory licensing law was decreased production costs and lower overall costs for numerous drugs in the American pharmaceutical industry.²¹⁵ Specifically, Brazil’s actions and its increased localized production of the medicines resulted in more affordable prices for certain critical HIV/AIDS drugs.²¹⁶ The United States dropped the issue because it did not

207. Mugabe, *supra* note 192.

208. *Id.*

209. *Id.*

210. Bate & Tren, *supra* note 74.

211. Bird & Cahoy, *supra* note 68, at 418.

212. *Id.*

213. *Id.*

214. SAMPATH, *supra* note 45, at 42.

215. Bird & Cahoy, *supra* note 68, at 418.

216. *Id.*

want to deal with the bad publicity, not because it was making any kind of concession or recognizing Brazil's rights to preserve and regulate its indigenous resources.²¹⁷

But it is possible that following Brazil's recent actions, debate between the United States and Brazil may once again be remembered and international attention will again be focused on Brazil's actions taken in asserting and protecting its indigenous resources.²¹⁸ In May 2007, Brazil's president Luiz Inácio Lula da Silva took what was considered an extreme action when he issued a compulsory license that bypassed Merck's patent on the HIV drug Sustiva and in effect overturned or cancelled patent protection the company once had.²¹⁹ The president's action was recognized as a bold step by both developed, industrialized nations as well as undeveloped nations.²²⁰

The Brazilian decision may have the potential to drive away industrialized countries' investment in Brazil because many companies may have fears of losing patent protection.²²¹ On the other hand, it might encourage developing countries to assert their own intellectual property regulations²²² in spite of the TRIPS Agreement, which actually serves to encourage companies to make patent claims on traditional knowledge or resources.²²³

Under the CBD, a developing country's regulations aimed at protection of and control over production of its natural resources, such as Brazil's recent action based on its compulsory licensing, would be completely acceptable and even encouraged.²²⁴ Because the result of the cancellation of that patent was again more affordable HIV/AIDS drugs, it is unlikely the United States or any other industrialized nation would take action to speak out against Brazil's use of compulsory licensing.²²⁵

But hopefully the positive impact of Brazil's actions on helping to provide effective, affordable drugs worldwide while still allowing for local regulation of indigenous resources will again bring focus to the issue of whether or not TRIPS truly is an effective international agreement. And perhaps the CBD and Brazilian focus on maintaining local procedures and local control of regulations regarding patenting and the requirement that indigenous knowledge be recognized and benefits be shared will be

217. See Yerkey & Pruzin, *supra* note 115.

218. See *Breaking Merck Patent May Drive Investment away from Brazil*, Pharmaceutical Business Review, May 9, 2007, http://www.pharmaceutical-business-review.com/article_feature.asp?guid=8A869BFC-88A5-4131-8CA3-231EE6F6E46C.

219. *Id.*

220. *Id.*

221. *Id.*

222. See *id.* Estimates show that as a result of bypassing Merck's patent Brazil will save nearly \$30 million in 2007 alone and "will cut \$237 million from its HIV/AIDS drug bill through 2012, when the patent right would expire." *Id.*

223. SAMPATH, *supra* note 45, at 43.

224. *Id.* at 39.

225. Bate & Tren, *supra* note 74.

recognized as the best policy for intellectual property regulation from the international perspective.

